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EXAMINER

SWARTZ, R

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

01/30/01

Pl ase find below and/or attached an Office communication concerning this application or
pr c eding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/064,682

Applicant(s)
Petersen

Examiner
Rodney P. Swartz, Ph.D.

Group Art Unit
1645



☒ Responsive to communication(s) filed on 13 November 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3 and 5-26 is/are pending in the application.

Of the above, claim(s) 21-26 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3 and 5-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-3 and 5-26 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's Response to Office Action, received 13 November 2000, paper #14, is acknowledged. Claim 12 has been amended.
2. Claims 1-3 and 5-26 are pending. Claims 21-26 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to a non-elected invention.
3. Currently, claims 1-3 and 5-20 are under consideration.

Rejections Withdrawn

4. The rejection of claims 1, 2, and 5-20 under 35 U.S.C. 112, first paragraph, scope of enablement is withdrawn.

Applicant argues that it has been known in the art that LTB binds to the same receptor in the gut as CTB. Applicant provides additional evidence, i.e., a publication by Backstrom et al, and a Declaration under 37 C.F.R. §1.132 by Jacob Sten Petersen, in support of applicant's argument that one skilled in the art would find guidance to substitute unconjugated LTB for CTB.

The examiner has considered applicant's argument, and in light of the publication by Backstrom et al and the Petersen Declaration, finds the argument persuasive.

5. The rejection of claims 12, 13, and 14 under 35 U.S.C. 102(e) as being anticipated by Holmgren et al (U.S. Pat. No. 5,681,571) is withdrawn in light of the amendment of the claims.

Applicants argue that Holmgren et al have published elsewhere that they do not find any effect on oral tolerance induction using only a mixture of CTB and antigen in an unconjugated form.

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Rejections Maintained

6. The rejection of claims 1-3 and 5-20 under 35 U.S.C. 103(a) as being unpatentable over JP3109328 in view of Elson (*Current Topics in Microbiology*, 146:29-33, 1989) is maintained.

Applicants argue that giving bone marrow cells by the oral route would result in degradation of the cells in the stomach or gut and therefore frustrate the purpose of the method specified in JP3109328.

The examiner has considered applicants' argument, but does not find it persuasive. The Japanese document is utilized to demonstrate that CTB when administered with a substance which normally results in an immune response (graft rejection of bone marrow cells) abrogates the normal rejection. The Japanese document is not utilized as a reference for oral administration.

Applicants argue that Elson teaches away from the instant claims by stating that CT feeding does not induce oral tolerance. Elson discloses that it is very important that the antigen be given by the same route and even at the same time as CT or CTB.

The examiner has considered applicants' argument, but does not find it persuasive. Elson teaches that cholera toxin as an oral (i.e., mucosal) adjuvant when conjugated with an antigen, but that intestinal administration of mixtures of CTB plus antigen would not stimulate antibody response to the latter in the intestine or in serum.(page 31, first paragraph and second paragraph)

Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to administer CTB as a mixture with an antigen to result in immunotolerance or immunosuppression of an immune response to said antigen.

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Conclusion

7. No claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


9. This application contains claim 21-26 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CAR 1.144) See MPEP § 821.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P. SWART, PH.D.
PRIMARY EXAMINER
Art Unit 1645

January 27, 2001